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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,573	09/30/2003	Michel H. Malek	036163-0101	9969

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EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/675,573

Applicant(s)

MALEK, MICHEL H.

Examiner

Suba Ganesan

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 12-15, 17, 18 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 16, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim **12** is rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (U.S. Pat. No. 6,454,807). Jackson discloses a fusion cage system (**1**) comprising a first leg (**10**) and a second leg (**11**). A tapped bore is defined by base (**12**). An insert (**13**) engages the threaded bore of the base (**12**). The first leg (**10**) and second leg (**11**) comprise the tapped bore of base (**12**).
2. Claims **22-24** are rejected under 35 U.S.C. 102(b) as being anticipated by Daher (U.S. Pat. No. 4,657,550). Daher discloses a connecting piece (**5**) (a 'base') with a buttressing means (**8,9**) (a superior and inferior 'vertically adjustable support') adjustably mounted onto the base using a threaded connection, with a tenon (a first and second 'intervertebral disc prosthesis') (**14,15**) mounted onto the buttressing means (**8,9**). The height of the tenon (**14,15**) can be adjusted by rotating the buttressing means (**8,9**).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims **13** and **14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim **12** above, in view of Jackson (U.S. Pat. No. 6,685,742).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, **10** and **11**) comprising a tapped bore (**12**) engaged by an insert (**13**). However, Jackson '807 does not disclose a joint disposed between the first and second baseplates, and further does not disclose a cup-knob joint disposed between the first and second baseplates. Jackson '742 teaches the use of a cylindrical pivot member (**34**) and a knuckle (**60**) disposed between the first and second legs (**10** and **11**) for the purpose of articulation. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with a cylindrical pivot member (**34**) and knuckle (**60**) in order to provide for articulation of the device.

4. Claim **15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim **12** above, in view of Jackson '742 and further in view of Bryan.

Jackson '807 and Jackson '742 disclose the same as above. However, Jackson '807 in view of Jackson '742 does not disclose baseplates with cups disposed thereon and a convex surfaced disc insert disposed between the cups. Bryan teaches upper and lower members (**104** and **106**) defining arcuate surfaces surrounding a central member (**108**) for the purpose of articulating along two convex surfaces. Therefore it would have been obvious to one of ordinary skill in the art at the time of this invention to modify the ball and socket joint of

Jackson '742 with the arcuate surfaces (**104** and **106**) and central member (**108**) as taught by Bryan in order to at least enable articulation along two convex surfaces.

5. Claim **17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson, 807 as applied to claim **12** above, in view of Mashburn (U.S. Pat. No. 7,022,138).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, **10** and **11**) comprising a tapped bore (**12**) engaged by an insert (**13**). However, Jackson '807 does not disclose an aperture on a threaded rod or a matching aperture on the baseplate. Mashburn teaches the use of a circumferential threadless aperture (**23**) on a threaded shaft (**17**). The circumferential threadless aperture (**23**) matches a threaded aperture (**37**) on a sleeve (**28**) for the purpose of locking the threaded shaft (**17**) to the sleeve (**28**). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with an aperture (**23**) on a threaded shaft (**17**) in order to lock the shaft to the sleeve.

6. Claim **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim **12** above, in view of Cauthen (U.S. Pat. No. 6,019,792).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, **10** and **11**) comprising a tapped bore (**12**) engaged by an insert (**13**). However, Jackson '807 does not disclose an aperture on a threaded rod that extends over a vertebra when the disc prosthesis

assembly is in place in an intervertebral space. Cauthen teaches the use of an opening (32) on a threaded shaft of a fusion chamber (30). The opening (32) allows for an engagement means for the purpose of connecting the implant device to a vertebra (see figure 4b). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with an opening (32) on a threaded shaft (30) in order to connect the device to a vertebra.

7. Claim 25-26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daher in view of Bryan.

Daher discloses the invention substantially as claimed including a connecting piece (5) (a 'base') with a buttressing means (8,9) (a superior and inferior 'vertically adjustable support') adjustably mounted onto the base using a threaded connection, with a tenon (a first and second 'intervertebral disc prosthesis') (14,15) mounted onto the buttressing means (8,9). Daher further discloses a central collar (between threads 18 and 19 in fig. 2) that divides the base (5) into an upper threaded section 18 and a lower threaded section 19. However, Daher does not disclose a disc insert capable of articulating with convex surfaced cups. Bryan discloses upper and lower members (104 and 106) defining arcuate surfaces surrounding a central member (108) capable of articulating along surface (132) for the purpose of simulating the motion of a natural intervertebral disc. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tenon (14,15) of Daher with the arcuate surfaced upper and lower members (104,106) and central

member (108) of Bryan in order to simulate the motion of a natural intervertebral disc.

Claim Objections

8. Claim 16, 27, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

9. Claims 1-11 and 19-20 are allowed.

Response to Arguments

10. Applicant's arguments filed on 10/16/2006 have been fully considered but they are not persuasive.

In view of the allowance of Claims 1-11 and 19-20, applicant's arguments with respect to those claims are moot.

11. With respect to claim 12-14, applicant argues that Jackson and Jackson'742 fail to teach threaded grooves on a first and second baseplate. Applicant acknowledges that Jackson teaches grooved bearing surfaces that mate to form an anterior channel. Applicant alleges that these grooves are not threaded. Examiner asserts that base 12 defines a threaded groove that is extending into the circumferential edge along the interior surface of baseplate 10 and 11.

With respect to claim **15**, Jackson '742 is an articulated spinal fusion cage. While spinal fusion is not the same as disc replacement, the articulated fusion cage of Jackson '742 is configured to provide a range of motion that approximates spinal motion. This demonstrates that there is no mutual "teaching away" of technologies; one of ordinary skill in the art would find it obvious to modify Jackson '742 with the arcuate surfaces of Bryan, to enhance the articulation already present in Jackson '742 to better withstand forces within the spine.

With respect to claim **17** and **18**, Examiner is broadly interpreting the claim language to be an aperture on a threaded surface that faces or contacts a baseplate or vertebral wall. Mashburn teaches the use of an aperture on a threaded rod that contacts a baseplate. The device of Cauthen is an implant body that is threaded on its outer surface with an aperture **12** contacting the vertebral wall. The claim language does not positively recite further structural limitations.

12. With respect to claims **22-25**, in response to applicant's argument that Daher does not teach a intervertebral disc prosthesis, examiner notes that the prosthesis of Daher is designed to be implanted between vertebra in order to *replace* a natural intervertebral disc. The claim language as written does not positively recite a prosthesis that articulates and functions as a natural spinal disc would. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art

structure is capable of performing the intended use, then it meets the claim. In the instant application, the intended use is simply as an intervertebral disc prosthesis; this limitation is met by the structure of Daher.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 1/4/2006

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Brian E. Pellegrino", written in a cursive style.